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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/803,512

03/18/2004

Guy Rome

1016720019P

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07/22/2009

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EXAMINER

VU, QUYNH-NHU HOANG

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

07/22/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/803,512	Applicant(s) ROME, GUY	
	Examiner QUYNH-NHU H. VU	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-41 is/are pending in the application.
- 4a) Of the above claim(s) 34-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30-33, 40-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

Claims 34-39 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group II, and Species I-4, there being no allowable generic or linking claim.

Election was made **without** traverse in the reply filed on 4/27/09.

Applicant's election without traverse of Group I, Species 5 (Figs. 7A-C) in the reply filed on 4/27/09 is acknowledged.

Claim Objections

Claim 41 is objected to because of the following informalities: there are two claims 41 in the listing of claims. Please re-number second claim 41 to claim 42. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 30, 40-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Vailancourt (US 4,512,766).

Examiner interprets the "distal portion" is on the right hand side and the "proximal portion" is on the left hand side.

Vailancourt discloses a catheter assembly comprising: a catheter 19 (Fig. 1-2, 5) or 60 (Fig. 4) including at least one lumen; and a connector 10 including a distal end 18 attached to a proximal end of the catheter and a passageway in fluid communication with the at least one lumen, a proximal portion of the passageway including an engagement feature 13 or the located wherein the adaptor 40 inserted into the connector 10 (Fig. 2) configured to connect an end of an instrument to the connector, a distal portion

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of the passageway including a valve 30 having a closed proximal end with a slit 37 and an open distal end, the valve proximal end distal of the engagement feature.

Regarding claims 40-41, the connector 10 includes a tapered outer surface at a proximal end thereof; a syringe adaptor 40 including a distal end configured to slide over the tapered proximal end of the connector housing 10 and a proximal opening to receiver a male luer (Fig. 2).

Claims 30, 33, 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Lopez et al. (US 6,932,795).

Lopez discloses a catheter assembly in Figs. 8-9 comprising: a catheter 1416 including at least one lumen; and a connector 412 including a distal end attached to a proximal end portion of the catheter and a passageway in fluid communication with the at least one lumen, a proximal portion of the passageway including an engagement feature 470 configured to connect an end of an instrument to the connector, a distal portion of the passageway including a valve 418 having a closed proximal end with a slit 466 and an open distal end, the valve proximal end distal of the engagement feature in Fig. 9.

Lopez further discloses an O-ring 420.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 31-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vailancourt or Lopez.

Regarding claim 31, it is well established that a recitation with respect to the manner in which an apparatus is intended to be employed, i.e. the wall of the valve configured to guide a proximal end of a guide wire from the valve distal end through the slit in the valve proximal end, a functional limitation, does

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not impose any structural limitation upon the claimed apparatus which differentiates it from a prior art reference disclosing the structural limitations of the claim, see *In re Pearson*, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974).

In this case of *Vailancourt*, since the insert member 20 is able to insert in the valve 30, therefore, one skill in the art would recognize that the guidewire can be inserted through the valve 30. Also, it is well-known in the art to provide a guide wire in the system to view the location of device inside the body.

In the case of *Lopez*, since the slit valve 466 is opened, therefore, one skill in the art would recognize that the guidewire can be inserted through the valve 418. Also, it is well-known in the art to provide a guide wire in the system to view the location of device inside the body.

Regarding claim 32, *Vailancourt/Lopez* discloses the claimed invention except for that the connector comprise a material having a hardness in the range of about 90 Shore A to about 90 Shore D, and wherein the valve comprises a material having a hardness in the range of about 40 Shore A to about 60 Shore A.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the material of connector and valve as listed above, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Claim 33 is rejected under 35 U.S.C. 102(b) as being unpatentable by *Vailancourt* in view of *Appling et al.* (US 5,651,776).

Vailancourt discloses the invention substantially as claimed. *Vailancourt* does not disclose the engagement feature comprise an O-ring.

Appling discloses a similar device comprising: a catheter 52, a connector 12, 33; an engagement feature at portion 12; an O-ring 44.

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It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Vailancourt with an O-ring, as taught by Appling, in order to provide a particularly effective sealing arrangement.

Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lopez in view of Wilson et al. (US 6,921,396).

Lopez discloses the invention substantially as claimed. Lopez discloses that the engagement feature engage with a medical implement 428 such as syringe, but Lopez does not specifically that the implement such as a tip of the tunneler upon insertion of the tunneler tip into the proximal portion of the passageway.

Wilson discloses a catheter assembly comprising: a connector 12 including a distal end attached to a proximal end of the catheter 16 and a passage in fluid communication with the at least one lumen, a proximal portion of the passageway including an engagement feature configured to connect an end of an instrument to the connector; wherein the engagement feature engages a tip 42 of the tunneler upon insertion of the tunneler tip into the proximal portion of the passageway.

It would have been obvious at the time the invention was made to a person having ordinary skill in the art to modify the device of Lopez with a engagement feature engages a tip of the tunneler, as taught by Wilson, in order to provide a connection between the tunneler with the catheter device.

Response to Arguments

Applicant's arguments with respect to claims 30-33, 40-41 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quynh-Nhu H. Vu whose telephone number is 571-272-3228. The examiner can normally be reached on 6:00 am to 3:00 pm.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763

Quynh-Nhu H. Vu
Examiner
Art Unit 3763